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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,721	06/18/2001	Yair Reisner	01/21720	7956

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/01/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/881,721

Applicant(s)

REISNER, YAIR

Examiner

Michail A Belyavskyi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Restriction/Election Fax*.

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**DETAILED ACTION*****Restriction Requirement***

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-21, drawn to method of inducing tolerance to transplant and method of transplanting a transplant, classified in Class 424, subclasses 93.7.
- II. Claims 22-28, drawn to a method of predicting the veto activity of a population of cultures HPC, classified in Class 435, subclass 7.1.
- III. Claims 29-33, drawn to a method of isolating cells possessing veto activity, classified in Class 435, subclass 440.
- IV. Claims 34-41, drawn to a method of treating or preventing an autoimmune disease, classified in Class 424, subclass 93.71.
- V. Claims 42-45, drawn to a population of cells, classified in Class 435, subclass 325.

3. Groups I –IV are different methods. A method of inducing tolerance to transplant and method of transplanting a transplant, a method of predicting the veto activity of a population of cultures HPC, a method of isolating cells possessing veto activity, a method of treating or preventing an autoimmune disease differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups V and I-IV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a population of cells of Group I can be used in variety of different biological processes, for example to make a conditional medium.

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5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

### **Species Election**

6. This application contains claims directed to the following patentably distinct species of the claimed Invention I: wherein conditioning the recipient under conditions recited in the claim 2.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

The examination of would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. This application contains claims directed to the following patentably distinct species of the claimed Invention I: wherein donor selected from the group consisting of  
A) allogeneic donor, or  
B) xenogenic donor.

These species are distinct because their structure physicochemical properties are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species (A)-(E) in the method parameters and in the immunological reagents used would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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8. This application contains claims directed to the following patentably distinct species of the claimed Invention I wherein transplant is selected from the group consisting of

- A) cells,
- B) tissue, or
- C) organ.

These species are distinct because their structure physicochemical properties are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. This application contains claims directed to the following patentably distinct species of the claimed Invention II wherein myeloid-specific molecule is selected from the group recited in the claim 23.

These species are distinct because their structure physicochemical properties and mode of action are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. This application contains claims directed to the following patentably distinct species of the claimed Invention II wherein method is selected from the group recited in the claim 25.

These species are distinct with respect to ingredients, method steps, and endpoints.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable

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11. This application contains claims directed to the following patentably distinct species of the claimed Invention II wherein method is selected from the group recited in the claim 26.

These species are distinct because their structure physicochemical properties are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. This application contains claims directed to the following patentably distinct species of the claimed Invention II wherein myeloid phenotype is effected by:

- A) histological staining,
- B) functional cellular, or
- C) functional biochemical assay.

These species are distinct because their structure physicochemical properties and mode of action are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. This application contains claims directed to the following patentably distinct species of the claimed Invention III wherein binding moiety is selected from the group recited in the claim 30.

These species are distinct because their structure physicochemical properties are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable

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14. This application contains claims directed to the following patentably distinct species of the claimed Invention III wherein composition-of-matter specifically bind to a molecule selected from the group recited in the claim 32.

These species are distinct because their structure physicochemical properties are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

15. This application contains claims directed to the following patentably distinct species of the claimed Invention IV wherein composition-of-matter specifically bind to a molecule selected from the group recited in the claim 41.

These species are distinct because their structure physicochemical properties are different and a person of ordinary skill in the art would not envision one in view of the other.

The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

16. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

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17. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.  
Patent Examiner  
Technology Center 1600  
March 28, 2002

*Phillip Gambel*  
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PRIMARY EXAMINER

*TC 1600*  
*3/29/02*